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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,378	02/10/2004	Hideaki Tada	Q79834	1872

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EXAMINER
O'HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,378	TADA ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-30* is/are pending in the application.

4a) Of the above claim(s) *13-19 and 24-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *11-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 11-30 are pending in the instant application.

Election/Restrictions

2. Applicant's election with traverse of Group I drawn to polypeptides in the reply filed on September 8, 2006 is acknowledged. The traversal is on the ground(s) that claim 30 relating to a production process of the polypeptide should be included in Group I. This is not found persuasive because the production of the protein is dependent upon the cell transformed with DNA encoding the protein, and more properly belongs in the invention of Group II, since claim 30 is a method of using the invention of Group II.

Applicants also request rejoinder of Group II claims upon indication of allowable subject matter pursuant to MPEP §821.04(a). If the claims of Group I are allowable and the claims of Group II depend from or otherwise have all the limitations of the elected invention, the restriction requirement will be withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-19 and 24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Claims 11, 12 and 20-23 are currently under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on February 10, 2004 has been considered by the examiner.

Priority

4. Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed, and also the status. See 37 CFR 1.78. There appears to be an error in the statement "This is a Continuation Application under 37 C.F.R. § 1.53(b) of Continuation Application Under 37 C.F.R. § 1.53(d) filed May 19, 2003, which is a Continued Prosecution Application (CPA) of Application No. 09/380,276, filed August 27, 1999". There was no application filed May 19, 2003, and additionally, the status of application 09/380,276 should be updated (now abandoned).

Rejections under 35 U.S.C. §§101 and 112, First Paragraph

35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 11, 12 and 20-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 11, 12 and 20-23 are directed to isolated proteins comprising the amino acid sequences of SEQ ID NOS: 4 and 8, identified as OAFO65a and OAFO6513, respectively. The instant specification discloses that OAFO65a is a 417 amino acid protein, OAFO6513 is a 423 amino acid protein, and that the first 415 amino acids of the two polypeptides are identical. The specification also provides sequence alignments with known tumor necrosis factor receptors

(Fig. 1), and discloses that these two proteins are members of the tumor necrosis factor receptor family due to structural homology and the presence of conserved cysteine residues in the extracellular domain. Although the evidence is convincing that these polypeptides are probably receptors in the TNFR family, the proteins do not have any specific or substantial utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001. Pages 17-35 of the instant application describe the uses and methods of the invention, and state that the nucleic acids and proteins can be used in methods such as therapies including administration of the proteins and gene therapy in diseases or disorders such as various immune deficiencies, use in regulating growth and proliferation of T and or B lymphocytes, use in treating infections including HIV, hepatitis, malaria, cancers, allergic reactions and conditions, chronic inflammation, regulation of myeloid or lymphoid cell deficiencies, transplantation, tissue regeneration including nerve and brain tissue, Alzheimer's, Parkinson's and Huntington's diseases, stroke, use as a contraceptive, use in suppressing or enhancing bodily characteristics such as height and eye color, use as an analgesic, use in treating depression and violent behaviors, use in correcting enzyme deficiencies, among many other proposed activities and treatments. The specification also teach that the proteins can be used to identify downstream signal transmission molecules which interact with them, to screen agonists/antagonists, natural ligands, and the nucleic acids can be used to produce the encoded proteins and to screen for homologous genes. However, these are not considered to be specific or substantial utilities for either the nucleic acid molecules or the proteins encoded by them. Methods such as identification of ligands or use to recombinantly produce protein are considered general methods applicable to any nucleic acid/protein, and are not considered specific or

substantial. The assertion that the nucleic acids/and or proteins of the instant invention can be used in the treatment of diseases or disorders or to effect bodily change is also not a substantial utility, and is based on the assumption that the proteins are receptors in the tumor necrosis factor receptor family, which as a family are involved in myriad biological pathways and activities. Many proteins are members of evolutionarily related families, yet have diverse biological activities and functions. Although homology to the TNF receptor family and expression provides some evidence that the claimed protein is a member of the TNF receptor superfamily, it is not predictable what the function of the proteins of the instant invention are from this information. Whereas a broad class of enzyme such as the ligases have a general utility in such an application as ligation of DNA for cloning purposes and which is essentially applicable to all of the members of that class, the class of proteins known as TNF receptors do not have a common practical utility which is based upon a property common to all of the members of that class. Members of this superfamily bind to a large variety of different ligands, mediate different signals, are expressed in different cell types and modulate different physiological processes, and are involved in different diseases and/or disorders, and it is not predictable what the specific physiological function of a TNF type receptor is based on homology to other members of this family (Wallach, D. (2000) TNF ligand and TNF/NGF receptor families. In: Cytokine Reference (Joost J. Oppenheim and Marc Feldmann editors in chief, Academic Press (London), 377-411). Though the protein of the instant invention may be classified as a member of the TNF receptor superfamily, this does not automatically confer a specific and substantial utility to the protein, since there is diversity in the activities and biological functions of these receptors. There is no

ligand known to bind and activate the proteins, and the biological activities upon ligand binding are also not known.

There is no nexus between any of the diseases or disorders and the molecules of the instant invention. Given no disease state or any other function or activity known for the protein, the protein is not considered to have utility. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a protein which has undetermined function or biological significance, and the use of an orphan receptor to discover its ligand or properties does not constitute a specific, substantial utility. All of the biological activities of a protein need not be known to obtain a patent, but there must be some specific and substantial activity or function known. It is possible that after further characterization, this protein might be found to have a patentable utility, such as association with a specific disease. This further characterization, however, is part of the act of invention, and until it has been undertaken the Applicants' claimed invention is incomplete.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6.1 Claims 11, 12 and 20-23 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Even if the specification were enabling of how to use the DNA98853 polypeptide, enablement would not be found commensurate in scope with the claims. If one of skill in the art does not know how to use the proteins, the skilled artisan would clearly not know how to use homologues of the proteins that have 95% to the proteins disclosed in the specification.

6.2 Claims 11, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides having at least 95% homology with a protein of SEQ ID NOS: 4 or 8. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing

feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequences set forth in SEQ ID NOS: 4 and 8, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Pertinent Art

7. The art considered pertinent to the present application is Pearce, Database UniProt_7.2, Accession No. Q5VZF7, May 10, 2005, which discloses a polypeptide which is 99.6% identical to the polypeptide of SEQ ID NO: 4 of the present application. This is not considered prior art, as the effective filing date of the instant application is before that of the cited art. This reference is cited as the protein having the closest homology.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PRIMARY EXAMINER